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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,366	09/17/2003	Arnold R. Leiboff	461.1011	4568

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,366	<b>Applicant(s)</b> LEIBOFF, ARNOLD R.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) 5, 15 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16-22 and 34-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Notice of Amendment*

1. In response to the amendment filed on 08/25/2006, amended claim(s) 1-4, 6, 9, 12-14, 16, 17, 39, and 42, canceled claim(s) 23-32, withdrawn claim(s) 5, 15, and 33, and new claim(s) 44-45 is/are acknowledged. The current rejections of the claim(s) 1-4, 6-14, 16-22, 34-43 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-13, 16-22, and 34-45 rejected under 35 U.S.C. 103(a) as being unpatentable over Takami et al (US 6,402,688) in view of Crane (US 464,692) as broadly as structurally claimed.

4. Regarding claims 1-4, 13 and 16, Takami et al discloses an air introduction device as best seen in Figure 1, comprising: an elastomeric body (20) defining an interior space, comprising insertion and sealing means for enabling bodily orifice insertion, and having (a) a proximal portion (19) having a tapered tip having a smaller cross-sectional area than said proximal portion and adapted to be inserted into a bodily orifice of a person, (b) a distal portion, element (17) and the tubing within the pump,

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defining a lumen adapted to receive a connector of a inflation pump (13) to enable air to be directed from the inflation pump into and through said body, and (c) an expanded portion, the transition region between elements (19) and (17), having a larger size than said proximal portion, including a first truncated conical surface tapering from a circumferential portion having a largest diameter of said expanded portion to said proximal portion and a second truncated conical surface tapering from said largest diameter circumferential portion of said expanded portion to said distal portion, adapted to engage with a bodily orifice to limit insertion of said proximal portion and seal said body against the bodily orifice, and having insertion-limiting means for limiting insertion of said part of said body into a bodily orifice and occluding an opening of a bodily orifice (column 1 lines 4-8).

5. For claims 6-8 and 17, Takami et al discloses an air introduction device, wherein said distal portion has first and second arms (AT7 and AT8), said first arm defining a first lumen (the interior of AT8) adapted to receive a connector of an inflation pump (13), said second arm defining a second lumen, the interior of AT7, and including a constriction (36), and wherein said proximal portion and said expanded portion have a common central axis, as best seen in Figure 1, and said second arm of said distal portion has a central axis parallel to and offset from said common central axis of said proximal portion and said expanded portion, as best seen in Figure 1.

6. For claims 9-12, 14, 18-22 and 34-43, Takami et al discloses an air introduction device, wherein (a) said distal portion has first and second arms wherein said first arm defines a first lumen (the interior of AT8) adapted to mate with a connector of an

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inflation pump (13), said second arm defines a second lumen (the interior of AT7) and an opening (36) to an exterior of said body communicating with said second lumen, further comprising a pressure regulating and relief valve (38) and (b) the air introduction device comprises a signaling means or a means for generating an audible indication, a buzzer (49) comprising a bill-shaped extension (electromagnetic arms or flaps) that produces an audible signal when air is released, coupled to said second side arm for providing a signal when air is released via said valve (column 4 lines 44-53).

7. Takami et al discloses the claimed invention, as described above, except for (a) the expanded portion or insertion-limiting means including a circular portion having a largest diameter of the expanded portion and extending radially outward from the proximal portion around the entire periphery of the proximal portion, (b) the first and second arms of the distal portion connected to the expanded portion or insertion-limiting means of the body and each of the arms including a lumen and opening at an end opposite the expanded portion, and (c) the body is monolithic. Crane teaches an air introduction device, wherein (a) the expanded portion or insertion-limiting means (element a) includes a circular portion having a largest diameter of the expanded portion and extends radially outward from the proximal portion around the entire periphery of the proximal portion (as best seen in Figures 1 and 2), (b) the first (D) and second (F) arms of the distal portion connected to the expanded portion or insertion-limiting means of the body and each of the arms including a lumen (the bore of element a2 and element f) and opening (the openings associated with lumens element a2 and element f) at an end opposite the expanded portion, and (c) the body is monolithic (as best seen

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in Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the air introduction device as taught by Takami et al, with Crane for the purpose of configuring a rectally sealable device for increased patient safety and comfort during medical procedures requiring rectally inserted devices.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-4, 6-14, 16-22, and 24-43 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

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MAX F. HINDENBURG  
PATENT EXAMINER  
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